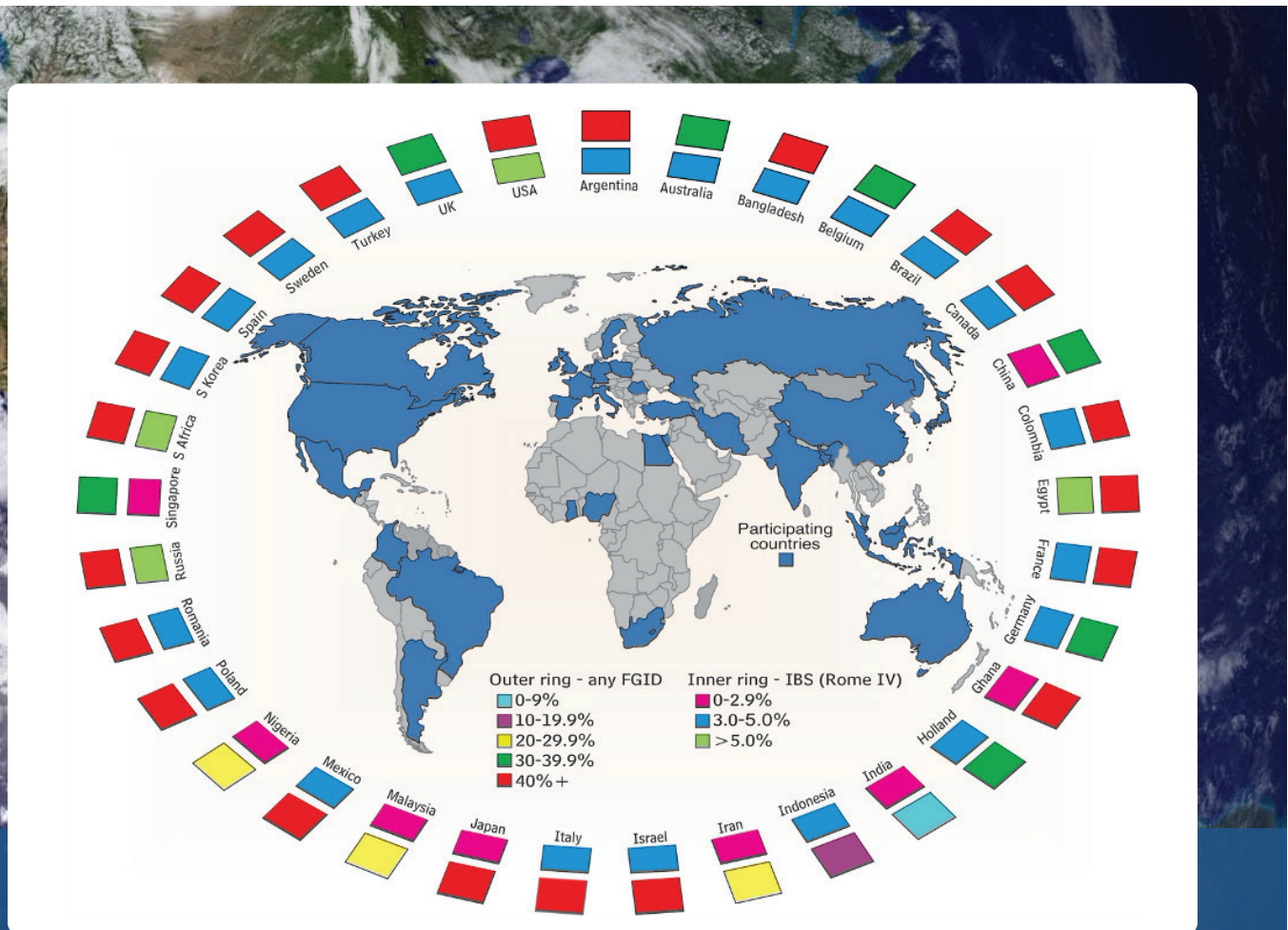


Our newsletters now link to even more information!
Just hover over each section and click on what interests you.



THE ROME GLOBAL EPIDEMIOLOGY STUDY

The idea for a Global Epidemiology study proposed by Ami Sperber, Rome Foundation Board Member, beginning in 2011. The plan was to use the new Rome IV diagnostic criteria to study the world-wide prevalence of Disorders of Gut-Brain Interaction, defined by the new criteria. Dr. Sperber worked out the details of the study design and then recruited investigators from around the globe to participate. The Rome Foundation received indispensable financial support for this global initiative from Shire, Allergan, and Takeda Pharmaceutical Company. The Rome IV study questionnaire was translated into 21 languages, localized into 18 additional versions (for example, Spanish was translated for Mexico and localized for Argentina, Colombia, and Spain) and underwent linguistic validation. The questionnaire was used as an online internet survey in 26 countries and a household door-to-door survey in 9 countries, with 2 countries using both methods. Read more about this nearly ten year endeavor inside.

FROM THE DESK OF THE PRESIDENT

Dear Rome Foundation Members, Friends, and Sponsors,

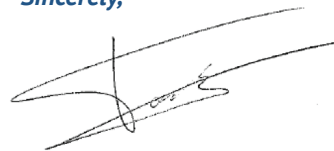
It is a tradition that many of you meet up with the Rome Foundation and its Board Members at the Digestive Disease Week of the American Gastroenterology Association. This year, with the Coronavirus pandemic, we will not have that opportunity, receiving our annual letter to review Rome Foundation over the past year and present to you our current and future initiatives is even more critical. We will also contact you for one on one conference to discuss plans and collaborations for the future.

This is the first time I am contributing to such a document. I took over the position of President almost one year ago from Doug, now Chief of Operations, and I can fully appreciate the accomplishments and broad range of activities and initiatives in which the Rome Foundation is involved. As you will learn from this letter, the Rome Foundation continues to promote awareness, education, and innovations to help patients, clinicians, and investigators better manage the Disorders of Gut-Brain Interaction (DGBI). We continue to work on previous ambitious initiatives together with the Rome Board of Directors and administrative staff. These include the Rome Global Epidemiology Study, advanced recent novel projects such as the Rome Foundation Research Institute and are starting many new programs and ideas. Our ultimate goal remains to improve the lives of people with Disorders of Gut-Brain Interactions.

This annual report starts with messages from the President and the Director of Operations and will focus on the following topics:

- The Global Epidemiology Study
- The Rome Foundation Research Institute
- The Communication Skills Initiative
- Copyrights and Licensing Program
- The GI Genius diagnostic and therapeutic aid
- Working teams
 - Post Infection Disorders of Gut Brain Interaction
 - Communication in Disorders of Gut Brain Interaction
- Plausibility of Pathophysiological Mechanisms
- Social Media
- Rome Educational Products overview
- Board news: Welcoming Brian Lacy and Farewell to John Kellow

Sincerely,



Jan Tack, MD, PhD
President, Rome Foundation



Learn from the World's Leading Experts to Understand and Explain to Patients Complex Issues in Disorders of Gut-Brain Interaction (DGBI)



EARN 3.0 CME CREDITS

This educational video series was developed by Douglas A. Drossman, MD, world-renowned expert in Gut-Brain Disorders and patient communication skills, in partnership with leading experts across the globe. The cutting-edge information offered in these videos is now available for provider and patient learning.

COMMUNICATION 101

- Thirty-two brief (5 minute) videos demonstrate how 15 thought leaders in Neurogastroenterology educate patients on common clinical issues
- The videos cover all major topics relevant to patients with DGBI
- This program can be used to educate clinicians to effectively communicate key messages, as a resource to show patients, or as a learning tool for patients

A Joint Initiative from  



“The experts in these videos clearly and concisely teach clinicians and patients about the complexities of these disorders. The feedback has been overwhelmingly positive.”
Douglas A. Drossman, MD

PRESIDENT EMERITUS AND COO REPORT

Dear Rome Foundation Members, Friends and Sponsors,

It has been a fantastic opportunity to assume this new position as Chief of Operations of the Rome Foundation and to work with Jan as the new President. Our newly created partnership has resonated with the needs of the Foundation to diversify the leadership in many ways.

First, after serving as President for almost 30 years, it is time for someone new to take over. Jan is the consummate clinician and scientist in the area of DGBI, he has terrific new initiatives planned, and he enhances our international presence. Under his leadership, we have and will continue to expand and enrich our mission and goals in many ways.

Second, it is no longer possible for one person to coordinate the growth of the Rome Foundation with all its activities. We are no longer the organization that produces a book of diagnostic criteria. In only five years, the Foundation has created so much: the Rome IV educational series of books and online products on DGBI, intelligent diagnostic and treatment software, communication skills training, data from the global epidemiological study with data from 33 countries, an expanded social media presence, the Rome Foundation Research Institute, a Psychogastroenterology section of mental health educators and investigators, a robust copyrights and licensing program, and a variety

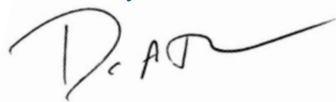
of educational activities to help providers of many disciplines. Thanks to Johannah Ruddy, our Executive Director, we have developed an administrative structure and support system that allows us to move forward on these programs seamlessly.

Third, we are moving toward Rome V. As co-senior editors, Jan and I have already begun the planning for an exciting new educational resource. Stay tuned as we ramp up on this new initiative.

Finally, I hope to use this new position as an opportunity to expand upon my creative and operational interests: to continue the communication program and validate their benefits through research publications, to develop innovative educational programs for clinicians, to expand our social media presence, to participate with Rome V and the RFRI, and to partner with many of our academic and industry sponsors.

What follows is a summary of our activities over the past year and the opportunities for the future. Jan and I look forward to working with you over the next year.

Sincerely,



Douglas A. Drossman MD



A Deeper Understanding of GI Illness Through a Patient-Centered Approach



EARN 3.25 CME CREDITS

COMMUNICATION 202 VIDEO SERIES

Program developed by Douglas A. Drossman, MD, world-renowned expert in Gut-Brain Disorders and communication skills. The methods have been taught at training programs internationally and are now available for self-learning.

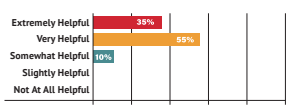
COMMUNICATION 202

- Learn to navigate your most challenging clinical cases and improve patient-provider satisfaction
- Optimize the patient-provider relationship and save time by learning effective communication skills
- Use our tips and techniques to successfully identify underlying fears and concerns, address treatment non-adherence, reduce conflict and increase patient engagement

A Joint Initiative from  

2019 Rome Foundation Survey of GI Faculty and Fellows

How positively do you believe this program will affect your practice?



“It's not what you do but how you do it that makes the difference.”
Douglas A. Drossman, MD



THE ROME GLOBAL EPIDEMIOLOGY STUDY

AMI D. SPERBER, MD, MSPH

The data was then collated by a biometry team, led by Drs. Kant Bangdiwala and Olafur Palsson. The first of many key publications is now in press in Gastroenterology, and it summarizes the prevalence of 22 Disorders of Gut-Brain Interaction across the globe and reports on their epidemiology and impact. Without the vision, persistence and motivational skills of Dr. Sperber, this would never have happened and the Rome Foundation as well as everybody working in or impacted by Disorders of Gut Brain Interaction is very grateful for this unique achievement.

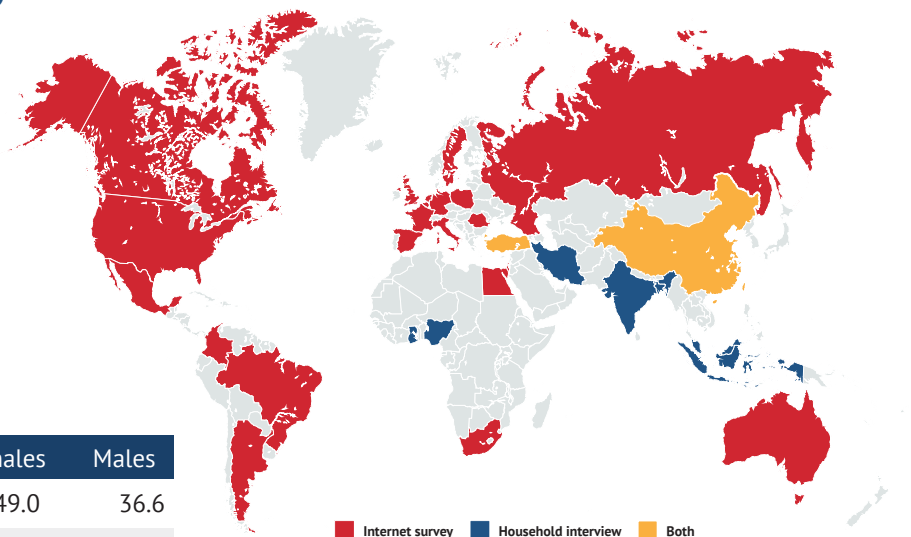
Reference of the publication of the Global Epidemiology study: [https://www.gastrojournal.org/article/S0016-5085\(20\)30487-X/fulltext](https://www.gastrojournal.org/article/S0016-5085(20)30487-X/fulltext)

A global epidemiological study of functional GI disorders

- 73,076 adults surveyed (33 countries, 6 continents)
- Data collection: By Internet (24 countries, red), by household interview (7 countries, blue), or both methods (China and Turkey, green)

Prevalence of meeting criteria for at least one of 22 functional GI disorders (%):

	All Participants	Females	Males
Internal Surveys	42.7	49.0	36.6
Household Surveys	21.6	24.1	19.0

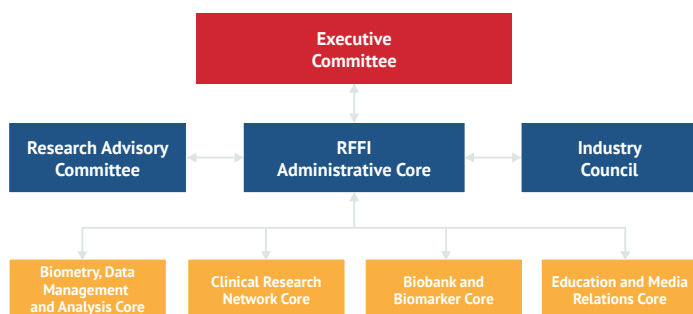


The global initiative database is now embedded in the Rome Foundation Research Institute database to allow data access and extraction for analysis, hypothesis generating and patient phenotyping for future research purposes. The full database consists of the answers to more than 170 questions by 73,076 adults from 33 countries. In each country, they closely match the composition and demographic characteristics of the adult population. The Rome Foundation Research Institute has developed a Policy and Procedures for Access to the Database, Conduct of Data Analyses, and Publications on the data. Doing so will ensure that more publications follow from this unique dataset, to further advance the scientific basis for understanding and managing Disorders of Gut-Brain Interaction. Further information on access to the database can be found on the website: <https://theromefoundation.org/research-institute-rome-foundation/rome-foundation-global-epidemiology-study/>.



The Rome Foundation Research Institute (RFRI) is a subsidiary organization of the Rome Foundation. It was created in 2018 to advance the scientific understanding of Disorders of Gut-Brain Interaction. The RFRI is a semi-autonomous entity that aims to conduct and support research on DGBI, and to be a global leader in this area of knowledge. Its mission is to improve the lives of patients with DGBI through ground-breaking research. The RFRI focuses on the following objectives to:

- Develop a centralized data acquisition and research coordinating center for DGBIs.
- Serve as an international clearinghouse for investigators and industry in the development, administration, and analysis of clinical research in DGBIs.
- Develop a portfolio of current and future study protocols and an accessible database of knowledge that can be adapted to address specific questions regarding DGBIs pathophysiology, impact, diagnosis, and treatment.



RFRI studies and activities.

Over the past year, the RFRI identified a Global Research Network of leading and highly productive investigators in the DGBI domain. The RFRI also engaged in several ongoing and planned research studies. These include the development of data analysis of the Rome Foundation Global Epidemiology Study, implementation of several clinical trials: the Domino and ROBOT studies, and a research project on bloating with Danone Pharmaceuticals. There are ongoing interactions with other companies on additional research projects. Below is a more detailed description of these studies.

CONTINUED ON NEXT PAGE

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1999-2006

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Callaghan, Australia
1990-2011

William E. Whitehead, PhD
Chapel Hill, NC, USA
1992-2018

Enrico Corazziari, MD
Rome, Italy
1989-2010



Creation of the Global Research Network.

An essential part of the mission of the RFRI is to establish an active Global Research Network of leading and highly productive investigators in the DGBI domain. These centers will coordinate their research efforts to produce compatible clinical datasets and biological samples on large numbers of DGBI patients. The centers will operate with a sufficiently uniform research methodology to make multi-center and multi-national research studies possible. To date, 91 investigators in 33 countries expressed their keen interest in joining the network (see figure 2). Many core centers will implement these aims in the ROBOT trial (see below).

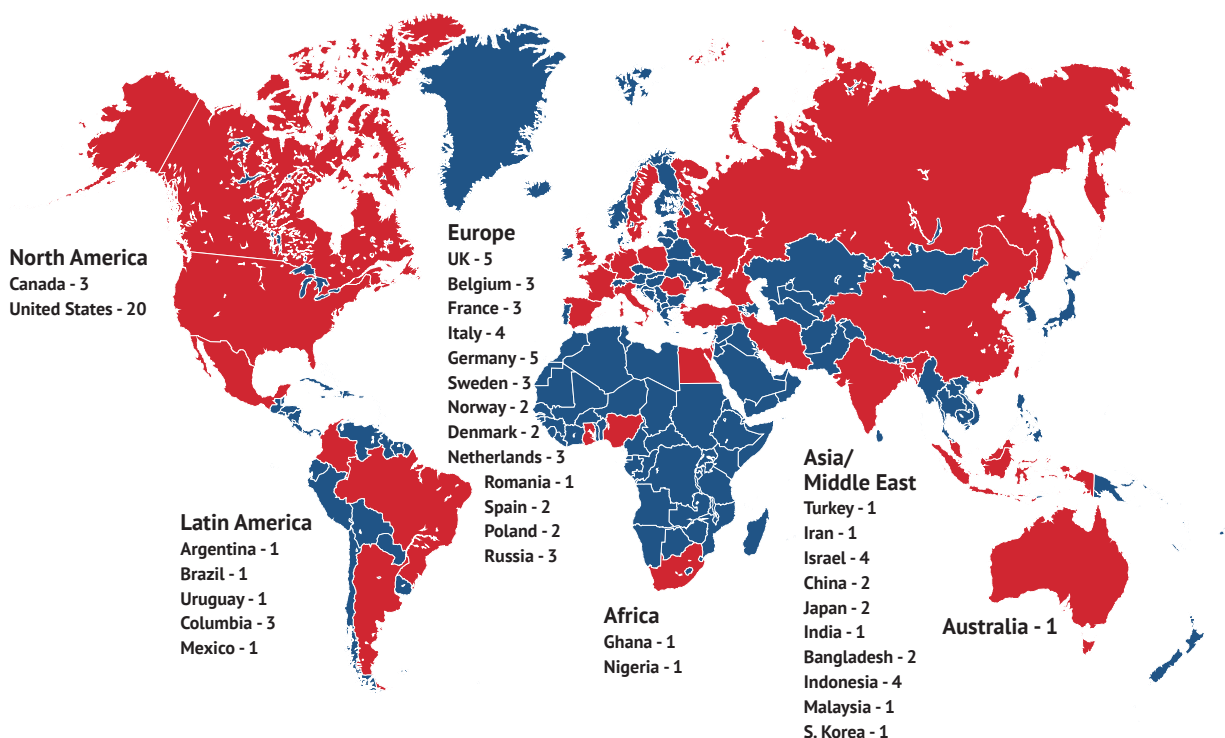
The full dataset of the Global Epidemiology Study is now integrated with the RFRI. These data will be a source for data extraction and further analyses and will also be integrated with other databases the RFRI is acquiring. The investigators of the global study also form

a worldwide network of FGID experts with a track record of research collaboration on a worldwide scale. The repository of translated versions of the Rome IV adult diagnostic questionnaire in the multiple languages used for the global study, including their linguistic validation (cognitive debriefing) and cultural adaptation, is an essential asset for future research efforts involving international participation.

Domino Trial

The DOMINO trial (Diet Or Medication in Irritable bowel syNdrOme) is a randomized study designed to evaluate the short-term efficacy and long-term health economic impact of a dietary intervention compared to pharmacotherapy with a muscolotropic spasmolytic agent for newly diagnosed or newly treated irritable bowel syndrome in primary care. This trial is funded by the Belgian Government, is pragmatic, and aims at optimizing primary care. It uses questionnaires that were developed for the Rome IV Global Epidemiology

World Distribution of RFRI Investigators 91 investigators in 33 countries



study in Belgium and also serves as an opportunity to collect biobank material from primary care IBS patients. Patients are randomized to treatment with OB 60 mg t.i.d., the traditional first-line medical therapy for IBS in Belgium, or by a FODMAP lowering diet, provided via a new smartphone application. Before and after 8 weeks of treatment, patients completed questionnaires evaluating demographics, stool types, Rome IV criteria, IBS-Symptom Severity (IBS-SSS), anxiety (GAD), depression (PHQ9) and somatization (PHQ15). By the end of 2019, the targeted 470 patients were enrolled, and 95% of the subjects provided biobanking samples for genetics, serum, and stool analysis. Patients with an improvement of at least 50 points on IBS-SSS are considered a responder. At baseline, 71% of these primary care-diagnosed IBS patients fulfill the Rome 4 criteria. (74% female, mean age 42 ± 0.9 years, and mean BMI of 24 ± 0.3). The following IBS-SSS distribution was found: 4, 16, 41, 39 % for normal, mild, moderate, and severe IBS-SSS, respectively. Patients were characterized according to the stool pattern: diarrhea (27%), constipation (23%), mixed stool type (38%) and normal (12%). The initial results of the study will be submitted for presentation at UEGW 2020.

ROBOT Project

The RFRI is initiating the ROme foundation BiOmarker and phenotyping project (ROBOT) in the first half of 2020. Initially, the study will start in a limited number of sites, to expand to more sites over the coming years. The ROBOT aims to develop a state-of-the-art biobank and database of patients with all types of DGBI, recruited from an international network of top international research sites. Patients in the database are thoroughly characterized in terms of clinical phenotype and associated demographic, medical history, psychosocial and lifestyle factors. Also, fecal, blood, and urine samples are collected and stored in a standardized fashion using common standard operational procedures. From a subset of patients, also biopsies from the upper and/or lower GI tract are collected depending on the predominant symptom profile. This growing collection of bio-samples and clinical/demographic data will enable evaluation of different biomarkers in large groups of very well-characterized individuals from different parts of the world and assessment of their validity for use as diagnostic and /or predictive tools. A centralized

electronic database will enable easy study of profiles of available clinical phenotypes and identification of available bio-samples to assess the feasibility of new research or analyses.

RFRI - Bloating Survey

This study focuses on symptoms of bloating and distention in the general population, acquiring data via a nationwide population-based Internet survey of adults in three countries: United States, Mexico and United Kingdom (2000 survey completers in each country). Quota-based sampling will be applied to obtain survey samples with the same age and sex groups composition in each country: 50% females and 50% males; 40% individuals of ages 18-39 years, 40% of ages 40-64 years, and 20% ages 65 and older. The subject sample in each country will also have nationwide geographic distribution.

The project research protocol is designed collaboratively by the RFRI and Danone, is subsidized by Danone, and is scheduled to be initiated in the second half of 2020. The a priori hypotheses to be evaluated are: (a) different personal factors and symptoms characterize the subset of individuals who report bloating or distention compared to those without these symptoms; (b) certain personal factors and symptoms distinguish bloating from distension that may reflect different pathophysiologic mechanisms; and (c) subgroups of individuals meeting Rome IV diagnostic criteria for Functional Abdominal Bloating/Distention will report only bloating or only distention and have different associated characteristics. Evaluation of data pertinent to the last hypothesis may yield identification of characteristic clinical features warranting subtyping of patients that may be amenable to different, more specific forms of treatment. Additionally, a sub-study in 1500 subjects (500 from each country) will address the relationship of bloating and/or distention symptoms with dietary factors in detail. The findings are also likely to help guide future refinement of the Rome diagnostic criteria for functional bloating and distention.

**NUTRICIA
RESEARCH**



Saturday, August 29, 2020 • 8:00am - 5:00pm



EARN UP TO 8 CE CREDITS**

Sponsored by



A One Day Virtual Event Basic Skills Training in Psychogastroenterology

A Rome Foundation Continuing Medical Education program

REGISTER TODAY at theromefoundation.org/gi-psych-training

One-Day Virtual Event • October 17, 2020 • 8:30am - 5:30pm



EARN UP TO 12 CE/CME
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The Rome Foundation Symposium On Disorders of Gut-Brain Interaction (DGBI)

Sponsored by



Formerly known as Functional GI Disorders (FGIDs)

for Physician Assistants, Nurse Practitioners,
Primary Care Providers, and All Other Clinicians Treating DGBIs
such as IBS, Functional Constipation, Functional Heartburn and more.

A Rome Foundation Continuing Medical Education program

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THE ROME- DROSSMANCARE COMMUNICATION SKILLS CURRICULUM

DOUGLAS DROSSMAN, MD

One of the more exciting new initiatives has been the development over the last year of a multimodal curriculum to teach communication skills to optimize the patient-provider relationship (PPR). This program is a collaboration between the Rome Foundation and the Center for Education and Practice of Biopsychosocial Care (DrossmanCare). The curriculum “What Do You Hear” has six components and is featured on our website <https://romedross.video/2KPTYzC>. We are most grateful to Ironwood and Salix Pharmaceuticals for their generous support of this Program. What follows is an update on these activities:

Educational Videos

Perhaps one of the best ways to educate clinicians on communication methods is to demonstrate them using video. To this end, we have produced two programs

- **Communication 202: A Deeper Understanding of GI Illness Through a Patient-Centered Approach.**

This innovative video learning tool teaches the sophistication and complexity of the medical interview. Within the context of a clinical visit, the program demonstrates educational techniques to improve communication skills, and patient-centered care, psychosocial assessment, shared decision making, and ways to optimize the patient-provider relationship. It consists of 6 clinical vignettes of patients with DGBI, and each is broken into four segments: an ineffective interview style, an effective interview style, the patient’s report of how they experienced the interview, and a step by step critique of the interview style. Communication 202 has been used at several conferences and for self-learning. In a survey of 20 users, 90% found that the program will be very or extremely helpful in their practice. The program is available at <https://romedross.video/2zebE5L>.

- **Communication 101: A Video Approach to Help Clinicians Rapidly Convey Key Clinical Messages to Patients with Disorders of Gut-Brain Interaction.** This newly released video learning tool is available for any clinician that treats patients with DGBI. Using

the expertise of 15 key opinion leaders in the field, we have them demonstrate in 5 minutes how they educate patients on 32 topics covering 11 content areas. Included are some of the most common clinical issues that arise in the course of a clinical visit. These include: “What is the Brain-Gut Axis,” “How do You Use a Secretagogue,” “How Do you Recommend a Patient to Go to a Mental Health Provider,” “What is a Neuromodulator,” “How to Explain Constipation and Dyssynergic Defecation” and many more. <https://www.communication101.org/vsl1586551670692>

Symposia and Webinars.

Over the last year, we have embedded communication skills training in international educational symposia, at major medical centers, AGA and ACG meetings, and our CME Regional educational programs. The table shows the responses to our Communication skills workshop at five of our CME regional programs. The percentages reflect a score of “excellent” using a five-point scale:

WORKSHOP ON COMMUNICATION SKILLS TO ENHANCE THE PROVIDER-PATIENT RELATIONSHIP

Douglas Drossman, M.D. & Johannah Ruddy, M.Ed.

% of attendees who rated each presentations aspect as Excellent*

	Santa Fe Oct. 2018 N=17	New York Jan 2019 N=15	San Antonio Feb. 2019 N=16	Myrtle Beach June 2019 N=11	Chicago Oct. 2019 N=17
Knowledge gained	88.8%	100%	100%	87.5%	91.7%
Presentation effectiveness	88.8%	100%	100%	100%	100%
The material presented was clear & understandable	100%	100%	100%	100%	100%
The information will be useful to me in my line of work	100%	92.9%	100%	80%	88.2%
The presenter seemed knowledgeable	100%	100%	100%	90%	100%
The handouts provided (when available) were useful	92.3%	100%	100%	90%	100%
The speaker met the objectives as stated	100%	100%	100%	90%	100%

**Ratings based on: Excellent, Very Good, Good, Fair, Poor*

THE ROME- DROSSMANCARE COMMUNICATION SKILLS CURRICULUM CONTINUED...

Educational Workshops for Faculty and Trainees at Medical Centers.

Over the last year, we have conducted workshops lasting from several hours to a full day training GI faculty and Fellows in communication skills using videos and small group learning methods, including role-play and Balint sessions. These programs were conducted at Johns Hopkins Medical Center in Baltimore, Mt. Sinai Hospital in NYC, and the University of Virginia in Charlottesville. The bar graph shows the responses of GI faculty at Johns Hopkins Medical Center regarding learning communication skills:

Educational Resources and Publications on Communication

We have produced a series of articles and other educational resources for clinicians and patients as seen here: <https://romedross.video/3blx535>

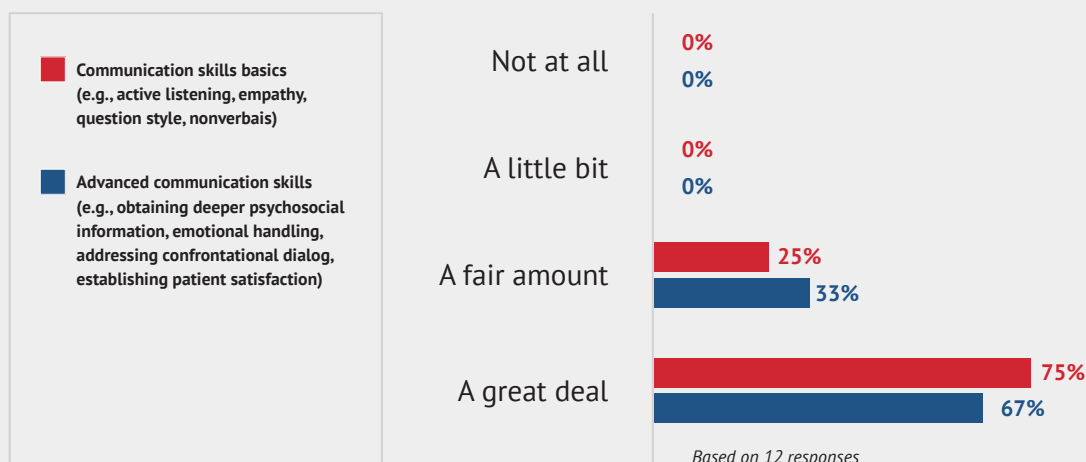
- Companion articles published in peer-reviewed journals highlighting the patient and provider experience.
- Videos by patient's telling their stories
- A downloadable study guide on tips and techniques to improve communication

- Podcasts
- Articles and videos on learning communication skills

Also, several other publications have been published or are upcoming:

- "Improving the Patient-Provider Relationship to Improve Health Care," in press Clinical Gastroenterology and Hepatology June 2020. This article by Doug Drossman and Johannah Ruddy provides a literature review and personal perspective on the challenges facing providers and patients with the constraints imposed by the current health care environment.
- "Communication Skills in Disorders of Gut-Brain Interaction." This article (Neurogastroenterology LATAM reviews 2019;2:1-14) by Doug Drossman and Johannah Ruddy briefly reviews the difficulties clinicians have in effectively communicating with patients. It then provides tips and techniques to improve the patient-provider relationship along with guidelines for patients on how to communicate better with their physicians. <https://romedross.video/32W6u7s>
- "The Influence of Communication Skills on the Patient-Provider Relationship: A review of the Evidence

How much participants learned in following areas:



and Recommendations for Implementation.” A new Rome Foundation Working Team is now underway. The committee members, all experts in this field, include Doug Drossman MD (chair), Lin Chang MD, Jill Deutsch MD, Alex Ford MD MBChB, Alben Halpert MD, Kurt Kroenke MD, Johannah Ruddy, M.Ed., Julie Snyder Psy.D. and Ami Sperber MD MPH. We plan to publish in early 2021.

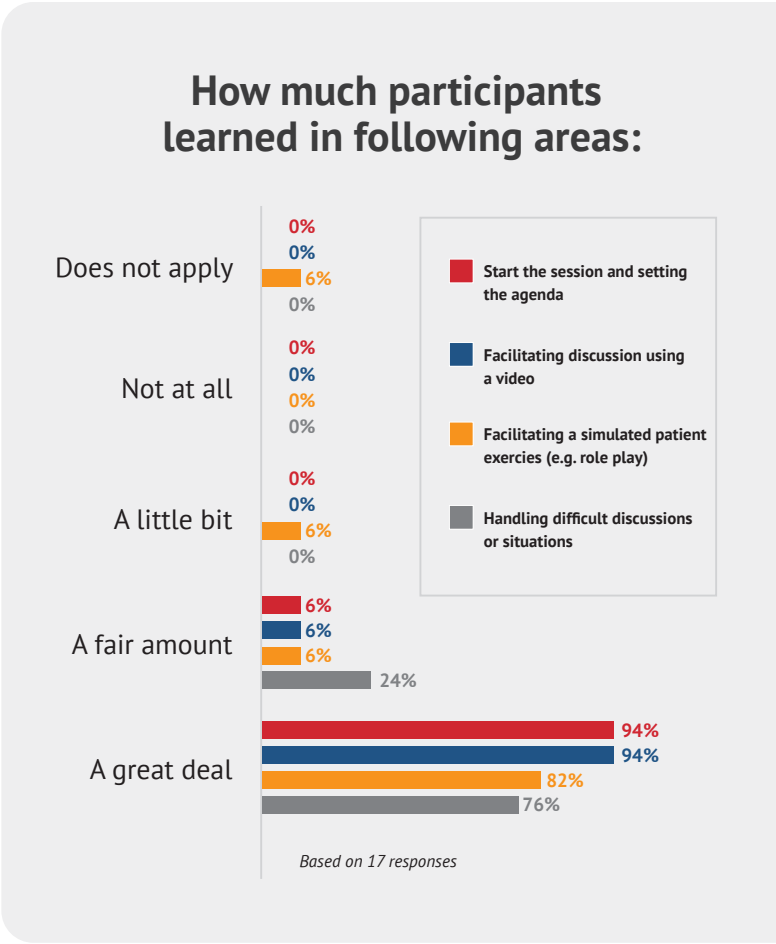
Train the Trainers Intensive Facilitation Education

The Train the Trainer program brings in thought leaders in DGBI to become facilitators at our future programs in communication skills. These individuals were selected based on their recognition as key opinion leaders, and educators, and they practice of patient-centered care. To date, we conducted two 6-hour sessions that involved teaching small group learning, using trigger videos, role play, and facilitating Balint type learning. Participants to date include Alben Halpert MD, Laurie Keefer Ph.D., Brian Lacy MD, Tony Lembo MD, Sam Nurko MD, Johannah Ruddy M.Ed., Jan Tack MD (Session 1) and Brooks Cash MD, Lin Chang MD, Bill Chey MD, Lucy Harris MD, Sarah Kinsinger Ph.D., Susan Lucak MD, Greg Sayuk MD, Magnus Simren MD (Session 2). This is a certification program, and the attendees are now qualified to co-facilitate future programs based on available funding. An additional Train the Trainer session was conducted for GI Faculty at Johns Hopkins Medical Center to enrich their fellowship training program. The following bar graph shows the responses of the participants to the facilitation components of the Train the Trainer Program.

Communication Research Program

Given the limited amount of published research that demonstrates the benefits of communication skills training, we have initiated a research component to our curriculum. Surveys of all programs are done online via online links or QR codes by the participants at the end of each session. Current results, as noted, indicate high levels of satisfaction.

Also, we are analyzing data from 173 patients at the Johns Hopkins GI clinic who were seen by the faculty that attended our communication skills program. Patients received validated questionnaires developed by Dr. Drossman: The Satisfaction with Care Scale and the



Physician-Patient relationship (PPR) Scale in addition to demographic and psychometric scales. Patient satisfaction with care was predicted using Multivariate and factor analytic methods. The patient data thus far show strong correlations between the patients’ perception of their physician and satisfaction. We have completed a factor analysis and will soon be publishing a reduced PPR scale that will predict patient satisfaction in clinical settings.

We intend to use these and future data to help us improve our programs, and to publish the results in peer-reviewed journals. These data will also provide us with crucial preliminary knowledge to develop a more comprehensive research proposal that we intend to carry out through the Rome Foundation Research Institute. Future research will assess whether the educational curriculum impacts patient satisfaction and clinical outcomes, procedures, health care utilization, and costs. We also plan to determine if our training improves clinician performance and if it is sustained over time.

Rome Copyright & Licensing of Research Instruments

The Rome Foundation has provided validated research questionnaires for licensing. However, recently the list of instruments available has expanded significantly. See Table for current instruments. We continue to acquire more and more Instruments for copyrights, translations and localizations of the various questionnaires for international research use. Due to the growing complexity of managing this licensing and distributino, the Rome Foundation formed a Copyright and Licensing Committee to organize the questionnaire offerings and streamline the licensing process. Substantial enhancements have already been made. Mark Schmitter, our marketing manager is the go to person to contact with questionnaires on licensing of these instruments. The committee members include Ami Sperber and Douglas Drossman as co-chairs, Olafur Palsson as chief of operations, and Iram Haq, as administrator.

Among the most commonly requested questionnaires for licensing include the Rome IV diagnostic questionnaires for adults and children, the Bristol Stool Form Scale, the IBS Severity Scale Score (IBS-SSS), and the IBSQOL. We now cover the vast majority of questionnaires used in DGBI research as well as for IBD, celiac disease aqnd others. Most all of the questionnaires have been developed for research by Rome Foundation members. These instruments are in stock in a wide variety of language and country adaptations. For example, the Bristol Stool Form Scale can now be obtained from the Rome Foundation in over 95 different translations and country adaptations. If you are a researcher, academician, clinician or student looking for validated research questionnaires in the functional GI area, your first stop should be the Rome copyright and licensing page, where you will see on our newly revised web form a list of the questionnaires you can get, and where you can directly request exactly what you need: www.theromefoundation.org/products/copyright-and-licensing/.

Licensing questionnaires from the Rome Foundation will require a licensing fee if you have funding for your project (for example, if you need the instruments for a

grant-funded research study or for commercial purposes). If you have no such funding, there is no fee for use of the questionnaires except a standard processing fee. Note, however, that you must have a license in order to use any and all of the questionnaires that the Rome Foundation offers, even if you are only going to use them in an unfunded project. We hope that you will take advantage of our ever-expanding resource of the Rome Foundation's questionnaire collection.

ROME FOUNDATION LICENSING OF RESEARCH INSTRUMENTS*

- Rome IV Adult and Pediatric Diagnostic Questionnaires
- IBS Quality of Life (IBS-QOL)
- IBS Severity Scale (IBS-SSS)
- Bristol Stool Form Scale, Adult and Pediatric (BSFS)
- IBS Global Improvement Scale (GIS)
- Satisfaction with Care (SAT 37)
- Functional Bowel Disorder Severity Index (FBDSI)
- Trauma Questionnaire (TC)
- Physician–Patient Relationship Scale (Patient and physician versions)
- Comorbid Medical Conditions Questionnaire (CMCQ)
- IBD Scales: UC/CD Health Status Scales, RFIPC
- Celiac Disease QOL (CD-QOL)

* Available in dozens of languages



Olafur Palsson, PsyD
*Operational Director of the
Licensing Committee*

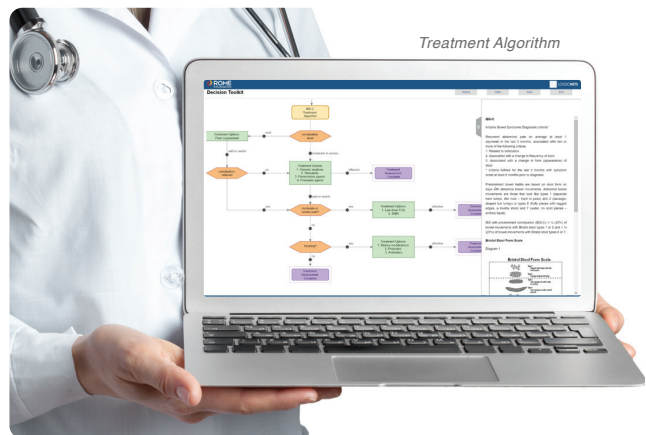


Iram Haq, MPH
*Research Coordinator for
RFR and the Administrator
of the Committee*

NEW PSYCHOSOCIAL AND TREATMENT UPDATES IN GI GENIUS INTERACTIVE DECISION MAKING TOOLKIT

The Rome IV GI Genius Interactive Clinical Decision Toolkit has continued to be updated!

In addition to updates to the scientific content for the treatment of Functional Gastrointestinal Disorders, we have made updates to the clinical information, and treatment recommendations for adults. To support these changes, additional references have been included throughout the program to help improve the user experience of our program. Additionally, we have updated the psychosocial treatment and evaluation portion of the program and added new information on central neuromodulators to help our users best serve the needs of their patients in a comprehensive way.



Furthermore, the Rome Foundation is excited to reveal the Pediatric Diagnostic and Treatment algorithms in our interactive toolkit.

Working with Dr. Samuel Nurko and other pediatric GI experts, the Rome Foundation has just released new diagnostic and treatment algorithms for neonate/toddler and child adolescents. Each of these new diagnostic and treatment algorithms is complete with up-to-date scientific information supporting each clinical decision, with supporting references. With these new updates, the Rome Foundation hopes to continue to serve as the gold standard for the diagnosis and treatment for all patients with FGIDs.

Samual Nurko, MD, MPH
*Co-Chair, Pediatric
Committee*



ROME FOUNDATION AWARDEES

AGA–Rome Foundation Functional GI and Motility Disorders Research Award.

This program provides two \$30,000 awards for novel pilot studies each year. For the full list of previous award winners, please see the Research Awards page on the Foundation's website at Rome Foundation Research Awards.

2020 AWARD WINNERS ARE:



Nitin K. Ahuja, MD, MS,
Assistant Professor, University of Pennsylvania, for the project: Shifts in the Gut Microbiome Following Dietary Modification in Irritable Bowel Syndrome



Bindu Chandrasekharan, PhD,
Emory University, for the project: Investigating the efficacy of probiotics to address opioid-induced constipation

Ray Clouse Prize for the Best Research Article on Functional Gastrointestinal and Motility Disorders.

This award honors the author of the best original research paper in the functional GI and motility disorders. The decision is based on scoring of the quality of the research by the Rome Foundation Board of Directors. The 2020 winner is:



Dr. Annette Fritscher-Ravens

Fritscher-Ravens A, Pflaum T, Mössinger M, Ruchay Z, Röcken C, Milla PJ, Das M, Böttner M, Wedel T, Schuppan D. Many Patients with Irritable Bowel Syndrome Have Atypical Food Allergies Not Associated with Immunoglobulin E. *Gastroenterology*. 2019 Jul;157(1):109-118.e5.

Ken Heaton Award for Paper Most Cited in Functional GI and Motility Disorders.

This award acknowledges the most frequently cited research paper published in 2018, based on the Web of Science citation count. Assessment is delayed by one year because this is the peak period for citations of papers. Papers by members of the Rome Foundation Board of Directors are ineligible. The 2020 winner is:



Peter Holger-Johnsen

Johnsen PH, Hilpüsch F, Cavanagh JP, Leikanger IS, Kolstad C, Valle PC, Goll R. Fecal microbiota transplantation versus placebo for moderate-to-severe irritable bowel syndrome: a double-blind, randomized, placebo-controlled, parallel-group, single-center trial. *Lancet Gastroenterol Hepatol*. 2018 Jan;3(1):17-24.

All awardees for 2020 will be recognized in 2021 at the DDW Rome Reception due to COVID-19.

The Rome Foundation – Aldo Torsoli Foundation Research Award.

This award was created in 2018 to recognize a mid or senior level MD or PhD who have an academic record of research, education and patient care in the area of gut-brain interactions (FGIDs). The 2020 winner is:



Alexander Ford, M.D.

Dr. Ford is professor of Gastroenterology at the University of Leeds. A postdoctoral research fellow at McMaster University in 2007, he is a proponent of evidence-based medicine, with an interest in disorders of brain-gut interaction (DGBI). His work, including several meta-analyses and systematic reviews, has informed management guidelines in both the UK and USA, and has informed treatment paradigms for several DGBI.

For a full list of previous winners of these awards, please visit our website at Rome Foundation Research Program.



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*Improving the lives of people
with functional GI disorders*



ROME FOUNDATION WORKING TEAMS

MOST RECENT WORKING TEAM REPORT



The Role of Brain Imaging in Disorders of Brain-Gut Interactions. A Rome Working Team Report.

Mayer EA, Labus J, Aziz Q, Tracy I, Kilpatrick L, Eisenbruch S, Schweinhardt P, van Oudenhove L, Borsook D. Gut 2019 Sep;68(9):1701-1715.

Imaging of the living human brain is a powerful tool to probe the interactions between brain, gut and microbiome in health and in Disorders of Brain-Gut Interactions (DBGI), in particular irritable bowel syndrome (IBS). While altered signals from the viscera contribute to clinical symptoms, the brain integrates these interoceptive signals with emotional, cognitive, and memory-related inputs in a non-linear fashion to produce symptoms. Tremendous progress has occurred in the development of new imaging techniques that look at structural, functional, and metabolic properties of brain regions and networks. Standardization in image acquisition and advances in computational approaches has made it possible to study large data sets of imaging studies, identify network properties and integrate them with non-imaging data. These approaches are beginning to generate brain signatures in IBS which share some features with those obtained in other often overlapping chronic pain disorders such as urological pelvic pain syndromes (UCPPS) and vulvodynia, suggesting shared mechanisms. Despite this progress, the identification of preclinical vulnerability factors and outcome predictors has been slow. To overcome current obstacles, the creation of consortia and the generation of standardized multisite repositories for brain imaging and metadata from multisite studies are required.

IN ADDITION, NEW WORKING TEAMS WERE INITIATED TO ADDRESS THE FOLLOWING TOPICS:

Working Team - The Influence of Communication Skills on the Patient-Provider Relationship: A review of the Evidence and Recommendations for Implementation.

This working team is chaired by Dr. Doug Drossman and involves an international multi-disciplinary panel of experts. The aim is to review the evidence for the influence of communication skills (verbal and nonverbal) on patient and provider satisfaction, adherence to treatment and clinical outcomes, and to provide guidelines for their implementation in clinical practice

Working Team on Behavioral Therapies in Disorders of Gut-Brain Interaction.

This working team was initiated by Dr. Laurie Keefer and involves a multi-disciplinary panel of experts who will address the current state and knowledge on behavioral therapies, provide guidance on the structure and format of key classes of therapy and what works best for whom, recommend earlier adoption of behavioral therapies and describe the range of conditions for which behavioral therapies have been effective.

Working team on the Plausibility of Pathophysiological Mechanisms in Disorders of Gut-Brain Interaction.

This working team was initiated by Dr. Jan Tack and is done in collaboration with the international societies on Neurogastroenterology and Motility to identify an international panel of experts who will address the current state and knowledge on relevant pathophysiological mechanisms underlying Disorders of Gut-Brain Interaction.

The Rome Foundation contributes to summarizing current knowledge and gaps in knowledge through the formation of Working Team Committees, who summarize the science and uncertainties relative to a defined topic. Working teams engage international participants who are experts in a particular area of interest to work together using a consensus (Delphi) approach to generate a manuscript for publication. Prior Working Team publications are shown in the attached table.

PREVIOUSLY PUBLISHED WORKING TEAM REPORTS

Post Infection IBS

Giovanni Barbara, MD, Chair, Madhusudan Grover, MD, Co-Chair

Gastroenterology, 156(1), 46-58.e47. 2019

Brain Imaging in DGBI

Emeran A. Mayer, MD, Chair, Qasim Aziz PhD, Co-Chair

Gut, 68(9), 1701-1715. 2019

Neuromodulators for FGIDs

Douglas Drossman, MD, Chair, Jan Tack, MD, PhD, Co-Chair

Gastroenterology, 154(4), 1140-1171.e1141. 2018

Pharmacological Trials in Children with Constipation

Miguel Saps, MD, Chair

Neurogastroenterology & Motility, 30(4), e13294. 2018

Multinational Cross-Cultural Research

Ami Sperber, MD, MSPH, Chair

Gut, 66(6), 1075-1082. 2017

Aliment Pharmacol Ther, 40: 1094-1102. 2014

Neurogastroenterol Motil, 26(10), 1368-1385 2014

Pharmacological Trials in Children with IBS

Miguel Saps, MD, Chair

Neurogastroenterology and Motility, 28(11), 1619-1631. 2016

Asian Working Teams for FGIDs

Kok Ann, Gwee MD, PhD Chair

William E. Whitehead, PhD Co-Chair

J Neurogastroenterol Motil, 21(1), 83-92. 2015.

Primary Care in FGIDs

A. P. Hungin, MD, Chair, Joel Heidelbaugh, MD, Co-Chair

Neurogastroenterol Motil, 27(6), 750-763. 2015.

Alimentary Pharmacology & Therapeutics, 40(10), 1133-1145. 2014

Food and Diet

William D. Chey, MD, Chair, Jan Tack, MD, PhD, Co-Chair

American Journal of Gastroenterology, 108(5), 694-697. 2013

American Journal of Gastroenterology, 108(5), 707-717. 2013

American Journal of Gastroenterology, 108(5), 748-758. 2013

American Journal of Gastroenterology, 108(5), 737-747. 2013

American Journal of Gastroenterology, 108(5), 718-727. 2013

American Journal of Gastroenterology, 108(5), 698-706. 2013

American Journal of Gastroenterology, 108(5), 728-736. 2013

Role of Intestinal Flora in FGIDs

Magnus Simrén, MD, PhD, Chair, Giovanni Barbara, MD, Co-Chair

Gut, 62(1), 159-176. 2013

Guidelines for Severity in IBS

Douglas Drossman, MD, Chair, Lin Chang, MD, Co-Chair

Am J Gastroenterol, 106(10), 1749-1759; quiz 1760. 2011

Guidelines for Brain Imaging in the FGIDs

Emeran A. Mayer, MD, Chair, Qasim Aziz, MD, PhD, Co-Chair

Neurogastroenterology & Motility, 21(6), 579-596. 2009

Outcomes/Endpoints in Pharmaceutical Clinical Trials

Michael Camilleri, MD, Chair

Gastroenterology, 137(6), 1944-1953.e1943. 2009

Rome Foundation Fellowship Program

The Rome Foundation Fellowship Program is our way of acknowledging Scientists and clinicians who have contributed their services to the Rome Foundation and have achieved international recognition for their work. Rome Foundation Fellows (RFF) are selected by a credentials committee, based on the following criteria:

Rome Foundation Clinical Fellow:

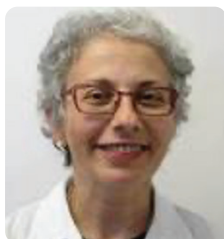
- Completion of clinical training in a well-established program
- At least 10 years of practice
- At least 3 first authored publications in peer reviewed journals
- Has worked with the Rome Foundation as a chapter, working team or committee member, and/or is well-recognized as a clinical leader in DGBI

Rome Foundation Fellows are permitted and encouraged to add the RFF designation on their signature line.

Rome Foundation Academic Fellow:

- Completion of a well-established research training program
- At least 10 years of research
- At least 10 first authored publications in peer reviewed journals
- Has been a primary recipient of 3 federal, or industry grants
- Has worked with the Rome Foundation as a chapter, working team or committee member, and/or is well-recognized as a clinical leader in DGBI

WE ARE PLEASED TO ANNOUNCE THE FOLLOWING AWARDEES FOR 2020:



Alben Halpert, MD
2020 Clinical Rome Fellowship
Awardee



Brooks Cash, MD
2020 Clinical Rome Fellowship
Awardee



Shin Fukudo, MD
2020 Academic Rome Fellowship
Awardee

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CHANGES TO THE ROME FOUNDATION BOARD OF DIRECTORS



Farewell to Dr. John Kellow

After 13 years of dedicated and outstanding contribution, Dr. John Kellow is retiring from the Rome Foundation Board. Dr. Kellow received his medical training at the University of Sydney and had research appointments at the Mayo Clinic, USA in 1984-1985, and at the Royal London Hospital Medical College, UK in 1986. Dr. Kellow returned to Australia where he is Associate Professor and Head of the Discipline of Medicine, Northern Clinical School, University of Sydney, and Gastroenterologist and Director of the Neurogastroenterology Unit at Royal North Shore Hospital, Sydney. Dr. Kellow has published extensively on disorders of gastrointestinal motility and the pathophysiology and treatment of the functional gastrointestinal disorders. As a Board Member, Dr. Kellow made several major contributions, including long-standing membership of the Finance Committee, and co-initiator of the Rome Algorithms project. We wish Dr. Kellow and his family all the best and good luck with their future plans.



Welcome to Dr. Brian Lacy

Dr. Brian E. Lacy, Ph.D., M.D., FACP, is joining the Rome Board in 2020. He is currently Senior Associate Consultant at Mayo Clinic Jacksonville and previously he worked at the Dartmouth-Hitchcock Medical Center where he was Section Chief of Gastroenterology and Hepatology and Professor of Medicine at the Geisel School of Medicine at Dartmouth. Dr. Lacy received his doctorate in cell biology from Georgetown University in Washington, DC, and his medical degree from the University of Maryland in Baltimore. Dr. Lacy was a resident in Internal Medicine at the Dartmouth-Hitchcock Medical Center in Lebanon, NH, where he continued his training as Chief Resident and as a Fellow in Gastroenterology. Dr. Lacy has a broad clinical and basic science research interest on disorders of gastrointestinal motility, and he has published over 175 peer-reviewed articles on these conditions, in addition to multiple text book chapters. Dr. Lacy is the current co-Editor in Chief of the American Journal of Gastroenterology. He is the former Editor in Chief of Clinical and Translational Gastroenterology. Dr. Lacy was the co-Chairman for the Rome IV Committee on Functional Bowel Disorders. He is the co-author of a book for the general public on acid reflux disease, "Healing Heartburn", is the author of "Making Sense of IBS", a book for the general public on irritable bowel syndrome, and edited and authored the books "Curbside Consultations in IBS", "Functional and Motility Disorders of the Gastrointestinal Tract" and "Essential Disorders of the Stomach and Small Intestine" for health care providers.

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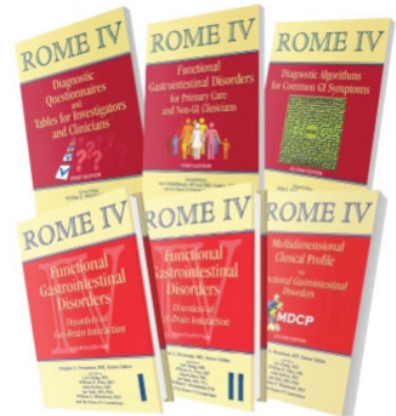
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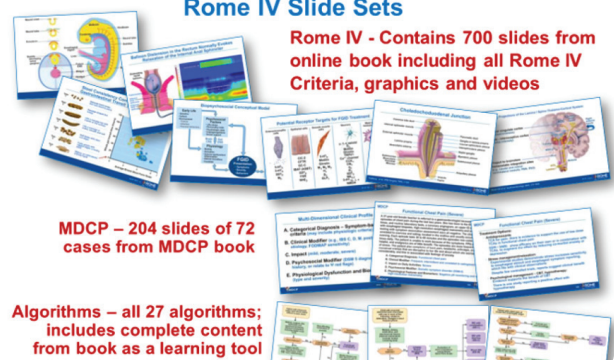
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- Rome IV algorithm slide set that includes 35 slides for presentation. Images can be purchased individually or as complete sets through our online bookstore, or individually through Rome IV online. Each multicolor image has a legend and up to date references; thus, sets are available for self-learning or for PowerPoint presentation at meetings and conferences.

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